REMARKS

Claims 1-10, 12, 35-44, 46-48, and 51-53 are pending in this application. Claims 1-10, 12, 35-44, 46-48, and 51-53 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 1-10, 35-44, and 48 are further rejected under 35 U.S.C. § 102(e) as being anticipated by Michaelis et al. (US2004/0034021, hereinafter "Michaelis"). By this reply, Applicants amend claims 1, 12, 35, and 48, and address each of the Examiner's rejections.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-10, 12, 35-44, 46-48 and 51-53 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In applying this rejection the Office states (page 2):

> The specific composition limited by the consisting language now recited in the claims is not envisioned. There is nothing in the specification pointing to this specific administration where rifalazil is administered only rectal[ly] or oral[ly].

Applicants respectfully traverse this rejection.

Applicants have amended claims 1, 12, 35, and 48 to recite "administered orally" or "orally administering." The present specification provides a written description for the oral administration of rifalazil alone. For example, the specification at paragraph [0023] states that the inventors "have discovered that administration of rifalazil alone or in combination with one or more additional antibiotics is effective to treat a subject" (emphasis added). Furthermore, at paragraph [0046], the specification provides a written description of "optimal dosages and formulations of rifalazil alone" (emphasis added). Further, Example 1 references an abstract, Anton P.M. et al., Abstract ID No. 102471, Publishing ID No. T1741, presented at the American Gastroenterological Association Meeting, May 17-22, 2003; Anton P.M. et al., Gastroenterology 124:A558, 2003, that

describes experimental results obtained following oral administration of rifalazil alone (by gavage), and evaluation of its efficacy against *C. difficile in vivo*. In view of these passages, it is clear that Applicants envisioned the oral administration of rifalazil alone for treatment of *C. difficile* at the time the application was filed. The rejection of claims 1, 12, 35, 48, and their dependent claims, under 35 U.S.C. § 112, first paragraph may be withdrawn.

Rejections under 35 U.S.C. § 102(e)

Claims 1-10, 35-44, and 48 are further rejected under 35 U.S.C. § 102(e) as being anticipated by Michaelis (US2004/0034021). The Office states (pages 3-4):

> Michaelis discloses a method of treating infection of clostridium difficile by administering a composition that comprises rifalazil; the composition that is administered may further contain one or more antibiotics.
>
> Michaelis does not exclude oral administration except that Michaelis preferred using parenteral administration...and...does not point to exclusionary use of parenteral administration.

Applicants respectfully traverse this rejection.

Applicants submit that Michaelis et al. is directed specifically to the intravenous administration of rifalazil. This is recited in US2004/0034021 at (a) the title "Intravenous Rifalazil Formulation and Methods Thereof," (b) the abstract "The invention features intravenous dosage formulations of rifalazil and methods of treating disease by intravenous administration of rifalazil," and (c) in claims 1, 9, 10, 12, 33, 36, 46, 48-53, and 59-60 (emphasis added). Nowhere in the claims of US2004/0034021 is found the administration of rifalazil orally. Further support for Applicant's contention that Michaelis specifically describes intravenous administration of rifalazil is also found throughout the specification beginning with paragraph [0005]: "We have discovered methods of formulating rifalazil for intravenous administration, as well as developing

compositions thereof, and methods of treating disease by administering rifalazil intravenously," and continuing through the specification at: (a) the Summary of the Invention, paragraphs [0006], [0009], [0011], [0012], [0014] - [0021], [0024] - [0035], [0037], [0046]-[0048], [0051], and [0054]; (b) the Detailed Description of the Invention, paragraphs [0082] - [0083], 1. Formulations, paragraphs [0084], [0085], [0087], [0111], [0114], and [0119], 2. Administration, paragraphs [0121] - [0125], and [0134], 3. Packaging, paragraphs [0144] - [0146]; and (c) the Examples, including the title of Example 2 "Formulation of Rifalazil for Intravenous Administration," and paragraph [0154] (emphasis added).

It is therefore clear from the specification that the invention described in Michaelis is directed solely toward the formulation and administration of rifalazil intravenously. There is no reference in Michaelis directed to the singular administration of rifalazil orally for the treatment of *C. difficile*, as presently claimed. Indeed, any mention of oral administration of rifalazil in Michaelis is merely to highlight the superiority of intravenous administration. For example, the specification at paragraph [0083] cited by the Office states that "it is often desirable to administer rifalazil parenterally, because of the lack of predictability in the bioavailability of orally administered rifalazil to diseased individuals. Intravenous administration is preferred." The superiority of intravenous rifalazil is further found in the Michaelis specification at paragraph [0121] which states that "intravenous dosage formulations provide clinicians with the ability to directly adjust the plasma levels of rifalazil to...result in superior ability to achieve a safer and more effective treatment of disease." Evidence of this is presented in Example 5, where the intravenous effective dose (ED_{50}) of rifalazil is half of the concentration required for the ED_{50} of oral rifalazil. Finally, Michaelis states in paragraph [0031] that when rifalazil is in different pharmaceutical combinations (e.g., other than rifalazil alone) and these are administered concomitantly with, or subsequent to, the initial intravenous administration of rifalazil, only then is oral administration taught as a therapeutic regimen. That is, oral

administration of rifalazil is taught only in combination with intravenous administration, not alone as presently claimed (emphasis added).

Thus, Applicants submit that the invention of the current claims was not disclosed by the Michaelis reference. Applicants respectfully request that the rejection under 35 U.S.C. § 102(e) be withdrawn.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested.

Enclosed is a petition to extend the period for replying for one month, to and including December 25, 2006. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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